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09/778,392	02/06/2001	Stefan G. Schreck	ECV-5620	4519

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EXAMINER	
RAGONESE, ANDREA M	
ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,392	SCHRECK ET AL.	
	Examiner	Art Unit	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on November 10, 2004 has been entered. Examiner acknowledges that **claims 1, 5, 23, 30, 38** and **45-47** have been amended.

Response to Arguments

2. Applicant's arguments with respect to **claims 1-52** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically discloses or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1-2, 5-7, 10, 20, 23-25** and **30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. (US 5,814,097).

Regarding **claims 1** and **30**, Sterman et al. discloses a system/method for performing a surgical procedure within a blood vessel, having at least one guidewire, as recited in column 15, lines 55-60 and column 16, lines 20-25, the guidewire is inserted into a body vessel; an antegrade probe having a distal portion and at least one antegrade guidewire lumen, the antegrade guidewire lumen terminating in at least one guidewire port (necessarily), as recited in throughout the specification with emphasis on columns 15-16 and more particularly column 15, lines 55-60; a retrograde probe having

a distal portion, the retrograde probe having at least one retrograde guidewire lumen the retrograde guidewire lumen terminating in at least one retrograde guidewire port (necessarily), as recited in throughout the specification with emphasis on columns 15-16 and more particularly column 16, lines 8-25, where the at least one retrograde guidewire port is co-aligned with the antegrade probe, as clearly shown in figure 34A; and at least one of the antegrade probe and the retrograde probe further comprising at least one lumen in addition to the retrograde and antegrade guidewire lumens, as recited in column 3, lines 60-65, column 5, lines 15-40 and 59-65, columns 15-16, column 18, lines 35-50, and column 19, lines 18-35.

Regarding **claim 2**, Sterman et al. discloses that as applied to **claim 1**, as well as, an antegrade probe and retrograde probe that are placed over the guidewire so that the guidewire resides within the at least one antegrade guidewire port and the at least one retrograde guidewire port and wherein the at least one retrograde guidewire port is co-aligned with the at least one antegrade guidewire port, as recited throughout the specification with emphasis on columns 15-16 and clearly seen in figure 34A.

Regarding **claim 5**, Sterman et al. discloses that as applied to **claim 1**, as well as, an antegrade probe and the retrograde probe that are each engageable with one of two pieces of tissue, to stabilize the tissue pieces, as seen in figure 34A.

Regarding **claim 6**, Sterman et al. discloses that as applied to **claim 5**, as well as, an antegrade probe and retrograde probe that are mutually engageable with the two pieces of tissue to stabilize the tissue pieces interposed therebetween, as recited throughout the specification and seen in figure 34A, for example.

Regarding **claim 7**, Sterman et al. discloses that as applied to **claim 1**, as well as, at least one lumen comprises a vacuum lumen, as recited in column 5, lines 20-35, column 15, lines 53-67, and column 19, lines 18-35.

Regarding **claim 10**, Sterman et al. discloses that as applied to **claim 1**, as well as, at least one of the distal portion of at least one of the antegrade probe and the retrograde probe that is substantially perpendicular to the longitudinal axis of the antegrade or retrograde probe, as recited throughout the specification and dependent on where it is in the deployment process, etc.

Regarding **claim 20**, Sterman et al. discloses that as applied to **claim 1**, as well as, at least one of the antegrade probe distal portion and the retrograde probe distal portion disposes at least one deployable alignment mechanism, as recited throughout the specification and wherein even a guidewire can be considered an alignment mechanism.

Regarding **claim 23**, Sterman et al. discloses that as applied to **claim 1**, as well as, at least one of the antegrade probe and retrograde probe having sufficient length, steerability and maneuverability which is fully capable of reaching a tissue within the blood vessel from a peripheral insertion site, as recited throughout the specification and seen in the drawings.

Regarding **claim 24**, Sterman et al. discloses that as applied to **claim 23**, as well as, a peripheral insertion site that is the femoral artery (84), as recited in column 15, lines 53-67.

Regarding **claim 25**, Sterman et al. discloses that as applied to **claim 23**, as well as, a peripheral insertion site that is the brachial artery, as recited in column 15, lines 53-67.

Sterman et al. teaches a system comprising all limitations recited in **claims 1-2, 5-7, 10, 20, 23-25** and **30**, but does not expressly discloses that the retrograde probe distal portion is position adjacent the antegrade probe distal portion. Applicant has not asserted that the specific arrangement of these two distal portions recited provide(s) a particular advantage, solve(s) a stated problem or serve(s) a purpose different from that of the stated prior art, thus the use of this structural limitation lacks criticality in its utilization and design. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the current configuration as show by the prior art of record. Therefore, it would have been obvious to modify the system of Sterman et al. by altering the retrograde probe distal portion to be adjacent the antegrade probe distal portion. Claims 1, 2, 5-7, 10, 20, 23-35, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Sterman et al. in US Patent No. 5,814,097.

5. **Claims 3-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. (US 5,814,097).

Regarding **claim 3**, Sterman et al. discloses that as applied to **claim 1**. However, Sterman et al. does not explicitly recite a second guidewire and wherein the antegrade probe comprises a first antegrade guidewire lumen terminating in a first antegrade guidewire port and a second antegrade guidewire lumen terminating in a

second antegrade guidewire port and the retrograde probe comprises a first retrograde guidewire lumen terminating in a first retrograde guidewire port and a second retrograde guidewire lumen terminating in a second retrograde guidewire port. On the other hand, it would be obvious to form any number of lumens in the tubular body. Therefore, it is within the scope of the invention and obvious to one with ordinary skill in the art to provide the system of Sterman et al with a second guidewire, wherein the antegrade probe has a first antegrade guidewire lumen terminating in a first antegrade guidewire port and a second antegrade guidewire lumen terminating in a second antegrade guidewire port where the retrograde probe has a first retrograde guidewire lumen terminating in a first retrograde guidewire port and a second retrograde guidewire lumen terminating in a second retrograde guidewire port for the purpose of enhanced alignment with additional guidewires.

Regarding **claim 4**, Sterman et al. as modified discloses that as applied to **claim 3**. However, Sterman et al. do not explicitly recite a first guidewire that resides within the first antegrade guidewire lumen and the first retrograde guidewire lumen and the second guidewire resides in the second antegrade guidewire lumen and the second retrograde guidewire lumen to align the distal portion of the antegrade probe with the distal portion of the retrograde probe. On the other hand, it would be obvious to one with ordinary skill in the art to use multiple guidewires to assure proper placement of the device and given the co-alignment having them interact would further be obvious to one with ordinary skill in the art.

6. **Claims 8-9, 11, 26-28** and **37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. (US 5,814,097) in view of Ferrari et al. (US 6,190,357).

Regarding **claims 8-9**, Sterman et al. discloses that as applied to **claim 7**. However, Sterman et al. do not explicitly recite at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the antegrade/retrograde probe, thereby enabling the grasping and manipulation of tissue. On the other hand, Ferrari et al. teach at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of a probe for tissue manipulation, in column 18, lines 55-60, and column 20, lines 36-46. Therefore, it would be obvious to one with ordinary skill in the art to modify the system of Sterman et al. to include at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the antegrade/retrograde probe that enables tissue manipulation for the purpose of properly grasping the valve.

Regarding **claim 11**, Sterman et al. discloses that as applied to **claim 1**. However, Sterman et al. do not explicitly recite a distal portion of at least one the antegrade probe and the retrograde probe that is tapered. On the other hand, Ferrari et al. teach a taper, as seen in figure 22. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include a taper for the purpose of enhanced access and vacuum.

Regarding **claims 26-27** and **37**, Sterman et al. discloses that as applied to **claim 1** and as modified **claim 36**. However, Sterman et al. do not explicitly recite a steering mechanism located proximate to the distal portion of at least one of the

antegrade probe and the retrograde probe and a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe, the steering conduit in communication with an operator through one of the at least one antegrade lumen and the at least one retrograde lumen. On the other hand, Ferrari et al. teach a steering mechanism located proximate to the distal portion of at least one of the antegrade probe and the retrograde probe, as recited in column 19, lines 15-42 and a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe, the steering conduit in communication with an operator through one of the at least one antegrade lumen and the at least one retrograde lumen. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include a steering mechanism for the purpose of enhanced movement control.

Regarding **claim 28**, Sterman et al. discloses that as applied to **claim 1**. However, Sterman et al. do not recite at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization. On the other hand, Ferrari et al. teach at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization, as recited in column 21, lines 1-3. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe, as taught by Ferrari et l. for the purpose of enhancing echo visualization.

7. **Claims 8-9, 12-19, 21-22** and **26-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. (US 5,814,097) in view of St. Goar et al. (US 6,629,534).

Regarding **claims 8-9**, Sterman et al. discloses that as applied to **claim 7**. However, Sterman et al. do not explicitly recite at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the antegrade/retrograde probe, thereby enabling the grasping and manipulation of tissue. On the other hand, St. Goar et al. teach at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of a probe for tissue manipulation, in column 9, lines 30-41, for example. Therefore, it would be obvious to one with ordinary skill in the art to modify the system of Sterman et al. to include at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the antegrade/retrograde probe that enables tissue manipulation for the purpose of properly grasping the valve.

Regarding **claim 12**, Sterman et al. discloses that as applied to **claim 1**. However, Sterman et al. do not explicitly recite at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe. On the other hand, St. Goar et al. teach at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe, as recited throughout the specification and abstract, column 4, lines 9-20, etc. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe, as taught by St. Goar et al. for the purpose of less invasive procedures.

Regarding **claims 13-19** and **32-35**, Sterman et al. discloses that as applied to **claim 1** and as modified that as applied to **claims 12, 17-18** and **31**. However, Sterman et al. do not recite a tissue fastener that is a suture-based tissue fastener; a tissue fastener that is a clip; a tissue fastener that is a staple; a tissue fastener receiver, the receiver providing cooperative stabilization of tissue while affixing the tissue fastener; at least one lumen comprises a tissue fastening lumen; at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe; and a tissue fastener that is a needle and suture. On the other hand, St. Goar et al. teach a tissue fastener that is a suture-based tissue fastener; a tissue fastener that is a clip; a tissue fastener that is a staple; a tissue fastener receiver, the receiver providing cooperative stabilization of tissue while affixing the tissue fastener; at least one lumen comprises a tissue fastening lumen; at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe; and a tissue fastener that is a needle and suture, as discussed throughout the specification. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one tissue fastener that is a suture-based tissue fastener; a tissue fastener that is a clip; a tissue fastener that is a staple; a tissue fastener receiver, the receiver providing cooperative stabilization of tissue while affixing the tissue fastener; at least one lumen comprises a tissue fastening lumen; at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe; and a tissue fastener that is a needle and suture, as taught by St. Goar et al. for the purpose of less invasive procedures.

Regarding **claim 21**, Sterman et al. discloses that as applied to **claim 20**. However, Sterman et al. do not recite at least two alignment arms flexibly attached to the distal portion of at least one of the antegrade probe and the retrograde probe; a deployment conduit operably connected to the at least two alignment arms; the deployment conduit attached to a deployment actuator; the at least two alignment arms having a retracted position wherein the arms are located proximal to the distal portion of at least one of the antegrade probe and the retrograde probe; the at least two alignment arms having a deployed position wherein the arms are extended radially from the distal portion of at least one of the antegrade probe and the retrograde probe; and the retracted and deployed positions achieved through manipulation of the deployment actuator. On the other hand, St. Goar et al. teach at least two alignment arms (such as 800, for example) flexibly attached to the distal portion of at least one of the antegrade probe and the retrograde probe; a deployment conduit (801) operably connected to the at least two alignment arms; the deployment conduit attached to a deployment actuator; the at least two alignment arms having a retracted position wherein the arms are located proximal to the distal portion of at least one of the antegrade probe and the retrograde probe; the at least two alignment arms having a deployed position wherein the arms are extended radially from the distal portion of at least one of the antegrade probe and the retrograde probe; and the retracted and deployed positions achieved through manipulation of the deployment actuator, as seen in figures 47A-47D, for example. Thus, it would be obvious to one with ordinary skill in the art to modify the

invention of Sterman et al. to include at least one the tissue fastener mentioned above, as taught by St. Goar et al. for the purpose of less invasive procedures.

Regarding **claim 22**, Sterman et al. as modified discloses that as applied to **claim 21**. Further, St. Goar et al. teach an alignment mechanism deployment lumen, wherein numerous tools function as alignment tools as recited throughout the specification.

Regarding **claims 26-27** and **37**, Sterman et al. discloses that as applied to **claim 1** and as modified **claim 36**. However, Sterman et al. do not explicitly recite a steering mechanism located proximate to the distal portion of at least one of the antegrade probe and the retrograde probe or a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe, the steering conduit in communication with an operator through one of the at least one antegrade lumen and the at least one retrograde lumen. On the other hand, St. Goar et al. teach a steering mechanism, as recited in column 3, lines 50-55. Thus, it would be obvious to modify the invention of Sterman et al. to have a steering mechanism as taught by St. Goar et al. for the purpose of enhanced movement and more precise location. This modification would necessarily yield a steering mechanism located proximate to the distal portion of at least one of the antegrade probe and the retrograde probe and a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe, the steering conduit in communication with an operator through one of the at least one antegrade lumen and the at least one retrograde lumen.

Regarding **claim 28**, Sterman et al. discloses that as applied to **claim 1**. However, Sterman et al. do not recite at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization. On the other hand, St. Goar et al. teach at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization, as discussed throughout the specification. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman et al. to include at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe, as taught by St. Goar et al. for the purpose of enhancing echo visualization.

Regarding **claim 29**, Sterman et al. discloses that as applied to **claim 1**. However, Sterman et al. do not recite a polymer coating, which can be wholly or selectively applied at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization. On the other hand, St. Goar et al. teach to enhance echo visualization. Thus, it would be obvious when modifying the invention of Sterman et al. to enhance echo visualization to include a polymer coating as a known way of enhancing echo visualization.

Regarding **claim 31**, Sterman et al. discloses the subject matter as applied to **claim 1** and as it applied to corresponding part of **claim 31**. However, Sterman et al. do not explicitly at least one tissue fastener at the distal end of either the retrograde probe or antegrade probe. On the other hand, St. Goar et al. teach tissue fasteners. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Sterman

et al. to include a tissue fastener at the distal end of either the retrograde probe or antegrade probe, as taught by St. Goar et al. for the purpose of performing less invasive procedures.

Regarding **claim 36**, Sterman et al. discloses the subject matter as applied to **claim 1** and as it applied to corresponding part of **claim 36**. However, Sterman et al. do not explicitly recite a steering mechanism located proximate to the distal end at least one of the antegrade probe and the retrograde probe. On the other hand, St. Goar et al. teach a steering mechanism, as recited in column 3, lines 50-55. Thus, it would be obvious to modify the invention of Sterman et al. to have a steering mechanism as taught by St. Goar et al. for the purpose of enhanced movement and more precise location.

Regarding **claim 38**, Sterman et al. discloses delivering an antegrade probe to a position antegrade to the tissue; delivering a retrograde probe to a position retrograde to the tissue; aligning the antegrade probe and the retrograde probe longitudinally; using one or more of the antegrade and the retrograde probes to stabilize the tissue. However, Sterman et al. do not recite using one or more of the antegrade and the retrograde probes to fasten the tissue. On the other hand, St. Goar et al. teach to fasten tissue. Thus, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Sterman et al. with the teachings of St. Goar et al. to incorporate tissue fastening through the probes for the purpose of less invasive procedure. This, combination would yield all of the steps of the method are that completed without arresting the heart.

Regarding claims **39-52**, Sterman et al. as modified by St. Goar et al. discloses that as applied to **claim 38**. Further, the combination would therefore, also yield that as applied to claims **39-52**. See the apparatus rejections stated above.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR
January 21, 2005

Henry Bennett
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